

REMARKS

The following remarks are submitted to be fully responsive to the final Official Action dated March 4, 2009. This response is thus timely submitted within the three-month shortened statutory period for response. Should any fees be required, the Commissioner is authorized to charge Kagan Binder Deposit Account No. 50-1775 and thereafter notify us of the same. Reconsideration of all outstanding grounds of the rejection and allowance of the subject application are believed in order and respectfully requested.

Claims 1-20 and 32-42 are pending in the application. Claim 15 has been withdrawn, and claims 21-31 have been canceled. Applicant's earlier arguments filed February 4, 2009 were found persuasive by the Examiner, and an earlier final rejection was withdrawn. Claims 1-14, 16-20, and 32-42 have been rejected based on a new final ground of rejection, as described below.

Applicant respectfully requests amendment of claims 1 and 32 as indicated above. In particular, the amendments of claims 1 and 32 clarify that "an oxygenated liquid flows from an outlet of the tubular member within the conduit and into the blood vessel." Applicants assert that the amendments do not, however, raise new issues. Based upon the rejections in the final Official Action, the Examiner was reading the previous claim language as indicating that the oxygenated liquid flows through the tubular member, but not out of the tubular member itself, and into the blood vessel, as in the present invention. Thus, the issue of whether the oxygenated liquid flows out of the tubular member was clearly at issue in the application when the final Official Action was mailed. Therefore, the amendments indicated above, being requested to clarify that oxygenated liquid flows from an outlet in the tubular member and into the blood vessel, do not raise any new issues.

Claims 1-3, 5-14, 16, 17, 32-34, 36-42 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. Patent No. 6,241,741 B1) and Blum (U.S. Patent No. 4,230,119).

Duhaylongsod et al. describes a fastener 10 with a graft vessel 12 attached, with the fastener 10 being first radially compressed for insertion within a slit in a side wall of an artery 14 (col. 7, lines 17-21, 25-26). Balloon catheter 80 is inserted through the graft vessel 12 and the fastener 10. Balloon 82 on the balloon catheter 80 is inflated to radially expand the end portion 20 of fastener 10 so that the graft vessel 12 sealingly engages an inner wall of the artery 14 to secure the fastener 10 within the artery 14 (col. 7, lines 21-25, 36-39). The balloon 82 is then

deflated and the catheter 80 is withdrawn from the graft vessel 12, leaving the vessel 12 coupled to the artery 14 (col. 7, lines 44-46).

In the final Official Action, the Examiner provided that Duhaylongsod et al. disclosed the method steps of independent claims 1 and 32, with the exception of providing an oxygenated liquid flow. The Examiner also provided that because oxygen flows through the catheter 80 in Duhaylongsod et al. and the catheter 80 is positioned within the blood vessel, oxygen is considered to flow into the blood vessel as claimed.

The Examiner's assertion that Duhaylongsod et al. discloses oxygen flowing into the blood vessel, as claimed, is erroneous. First, there is no mention in Duhaylongsod et al. that oxygen gas or a liquid including oxygen is used to inflate balloon 82 within the artery 14 and graft vessel 12. Second, even if oxygen gas or an oxygen-containing fluid is used to inflate balloon 82, it would not flow into the artery itself. There is no outlet in tubular member 80 shown or described. Any liquid or gas used to inflate the balloon 82 stays within tubular member 80.

The Examiner provided that Blum "teaches providing an oxygenated liquid flow (sterile saline solution) via a bulb (13) through the tubular member to expand its weakened distal regions," and that "it would have been obvious to one of ordinary skill in the art to substitute Duhaylongsod's oxygen flow with an oxygenated liquid flow."

Blum describes a micro-hemostat and methods of using the device. The micro-hemostat is described as including a T-shaped member having a highly flexible double walled tubular bar. A stem of the T-shaped member is connected at one end to an outer wall of the bar and communicates with an annular space between the two walls of the bar. The other end of the stem is connected and communicates with a pressure bulb containing a pressurized fluid to form a completely closed fluid system. The outer wall includes two expandable cuff portions adjacent to each end of the bar that are made of an elastic material. (Abstract). In use, the bar is inserted into a blood vessel through an incision, in an unpressurized state. The bar is then pressurized by squeezing the pressure bulb, which inflates the cuff portions. (Abstract).

The Examiner's assertions regarding Blum are erroneous. First, Blum does not disclose providing an oxygenated liquid, but instead discloses using a sterile saline as a pressurizing fluid (col. 3, lines 36-37). Second, the pressurizing fluid, even if it did contain oxygen, does not flow out of the tubular member and into the blood vessel. The micro-hemostat is a closed fluid system, and the fluid stays within the walls of the device in order to inflate the cuff portions.

Therefore, the combination of Duhaylongsod et al. and Blum do not teach or suggest all of the features of independent claims 1 and 32 of the present application. In particular, the method step of “fixedly joining the conduit . . . to the vessel wall . . . while providing an oxygenated liquid flow from an outlet of the tubular member . . . and into the blood vessel,” is not taught or suggested by the combination of references. Even if the “oxygen flow” of Duhaylongsod et al. was replaced with an “oxygenating liquid flow,” it would not result in the invention as claimed, since the liquid would not flow into the blood vessel, but would stay within a closed system of a tubular member. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1 and 32.

Independent claims 1 and 32 are patentably distinct from Duhaylongsod et al. and Blum for the reasons discussed above. Claims 2-14, 16-20, and 33-42 are dependent upon independent claims 1 and 32 and add further limitations to claims 1 and 32, and thus further add to the distinctness of the claimed invention. Thus, withdrawal of the rejection of record with respect to claims 2-14, 16-20, and 33-42 is therefore also respectfully requested.

Regarding independent claim 32, it is submitted that there are additional distinguishing features from Duhaylongsod et al. and Blum. The method described in claim 32 is an “end-to-end” anastomosis, which is different from an “end-to-side” anastomosis, which was the subject of claim 1, for example. Positioning the graft at or near the blood vessel proximal end, in claim 32, is done specifically for the purpose of performing an end-to-end anastomosis. An end-to-end anastomosis would not be possible if the graft was inserted at the position shown and described in Duhaylongsod et al. or Blum, which is into a side wall of a vessel. Thus, the method of claim 32 is further distinct from the technique of the Duhaylongsod et al. and Blum references, which do not disclose a graft connection or any other connection to or near an end of any blood vessel. So, in addition to distinguishing on a similar basis as claim 1, claim 32 is further patentably distinct regarding the end-to-end anastomosis that is created according to the claim steps.

Claims 4 and 35 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. and Blum as applied to claims 1 and 32 and further in view of Stanish (U.S. Patent No. 6,585,762 B1).

Claims 4 and 35 are dependent upon claims 1 and 32, respectively. Therefore, based upon the discussion above, claims 4 and 35 are similarly not rendered obvious by Duhaylongsod et al. and Blum. Stanish does not remedy any deficiencies of Duhaylongsod et al. and Blum in order to render claims 4 and 35 unpatentable.

In the final Official Action, with regard to claims 4 and 35, the Examiner provided that Duhaylongsod et al. and Blum fail to disclose fixedly joining, including suturing, the conduit to the blood vessel, and further provided that such suturing was disclosed by Stanish. The Examiner also provided that because Duhaylongsod et al. discloses that the conduit may be further secured to the vessel using an adhesive, that it would have been obvious to suture the conduit to the vessel in the method of Duhaylongsod et al., and Blum.

Stanish may disclose suturing of a graft to a vein, but the reference is not properly combinable with Duhaylongsod et al., as indicated by the Examiner. In Duhaylongsod et al., suturing of the conduit 26, 12 is not necessary or desired. For example, in the embodiment of Figures 5-8, the graft vessel 12 or conduit is attached to a fastener 10 that is expanded using a balloon catheter 80 in order to seal the graft vessel 12 to the artery. There is no need for sutures in that embodiment. Duhaylongsod et al. actually teaches away from using sutures to join a conduit to a blood vessel, and teaches the use of expandable fasteners instead. The specification of Duhaylongsod et al. even provides that an aspect of the invention is to allow two vessels to be “sealingly secured to one another without the need for sutures” (col. 1, lines 52-54). Using sutures of Stanish with the apparatus of Duhaylongsod et al. would result in the apparatus being unsuitable for its intended purpose, which is to secure two vessel together without sutures. Therefore, the combination of references does not render the claims obvious.

Accordingly, it is submitted that the Duhaylongsod et al. and Blum in further view of Stanish do not teach or suggest all the features of claims 4 and 35 and do not render claims 4 and 35 obvious. Withdrawal of the rejection of record with respect to claims 4 and 35 is therefore also respectfully requested.

Claims 18-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. and Blum in further view of Amor et al. (U.S. Patent No. 6,059,809).

Claims 18-20 are dependent upon independent claim 1. Therefore, based upon the discussion above, these claims are similarly not rendered obvious by Duhaylongsod et al. and Blum. Claims 18-20 are rejected as being unpatentable over Duhaylongsod et al. and Blum in further view of Amor et al. Amor et al., however, does not remedy the deficiencies of Duhaylongsod et al. and Blum in order to render claims 18-20 unpatentable.

In the final Official Action with regard to claim 18-20, the Examiner provided that Duhaylongsod et al. and Blum fail to disclose the step of inserting a stiffening member within the tubular member, and further provided that Amor et al. discloses a method comprising the step of “inserting tubular member (4) through a conduit (8) and into a vessel,” and that it “would have

been obvious to one of ordinary skill in the art at the time the invention as made to insert a stiffening member within Duhaylongsod's (in view of Blum) tubular member."

Amor et al. discloses a device used to implant or deliver stents to arteries. The device includes a stent pusher portion 2 comprising a microcatheter 4 with a guide wire 6 extending through a lumen 5 in the microcatheter 4. The device also includes a stent loading cavity 7 able to retain a stent 7, which is self-expanding. The distal end 9 of the device includes an atraumatic tip 10 which is prolonged by a tip balloon part 11 comprising an inflatable occlusive balloon 12 and a fluid releasing section 13. When the device is inserted into a body, the tip balloon part 11 leads the device. The shape of the tip balloon part 11, when the balloon 12 is deflated, is able to be changed to fit through the vascular system by advancement of the guide wire 6 more or less into the tip balloon part 11. The balloon 12 can be inflated to hermetically close the vessel upstream with respect to the stenosis to be cured.


Amor et al. does not remedy the shortcomings of Duhaylongsod and Blum with regard to independent claim 1. Therefore, similarly, claims 1-20 are also not rendered unpatentable by the combination. Further, in Amor et al., the guide wire 6 referred to by the Examiner is not a stiffening member but is instead a guide wire that changes the shape of occlusive balloon 12 when it is in a deflated state by being advanced more or less into tip balloon part 11 (col. 4, lines 12-17). Therefore, the guide wire 6 in Amor et al. does not teach or suggest the stiffening member features added by dependent claims 18-20. Accordingly, withdrawal of the rejection of record with respect to claims 18-20 is also respectfully requested.

It is further submitted that the cited references are specifically deficient with respect to the claims both as they were previously pending and even more so as pending with the present amendments. For clarification purposes, the Applicant respectfully requests entry of the amendments, as well as allowance of the pending claims.

Conclusion

Applicant submits that claims 1-20 and 32-42 are currently in condition for allowance, a notice of which is earnestly solicited. If the Examiner finds any issue remaining after consideration of this response, the Examiner is invited to contact the undersigned, at the Examiner's convenience, in order to expedite any remaining prosecution.

Respectfully Submitted,

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